

**Translation**

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**PATENT COOPERATION TREATY**

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**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>0D162PCT</b>	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. <b>PCT/JP2003/008568</b>	International filing date (day/month/year) <b>04 July 2003 (04.07.2003)</b>	Priority date (day/month/year) <b>05 July 2002 (05.07.2002)</b>
International Patent Classification (IPC) or national classification and IPC <b>A61K 33/00, 7/48, 7/00, 9/70, 47/04, 47/30, 47/32, 47/36, A61P 17/00, 17/02, 43/00</b>		
Applicant <b>NEOCHEMIR INC.</b>		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand <b>20 January 2004 (20.01.2004)</b>	Date of completion of this report <b>22 April 2004 (22.04.2004)</b>
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/008568

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished

- ☐ the description:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☐ the claims:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☐ the drawings:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/JP 03/08568

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

### 2. Citations and explanations

Document 1 (JP 2000-319187 A (Medion Research Laboratories), 21 November 2000) discloses inventions relating to "compositions containing water, a thickener and carbon dioxide in the form of bubbles, enabling persistent percutaneous or permucosal absorption of carbon dioxide" and states that such compositions "can be impregnated into an absorbent material such as gauze or sponge, or these materials can be formed into a bag and the composition inserted therein and affixed to the site of usage" (paragraph [0029]), and that "an even greater effect can be expected if combined with occlusive dressing, wherein the site to which said composition has been applied or attached is covered with a material such as a film or dressing which has poor permeability to air" (ditto), and presents "gum Arabic, carrageenan, etc," (paragraph [0037]), and "carboxyvinyl polymer, sodium polyacrylate, polyvinylacetal diethylaminoacetate, poly(vinyl alcohol) and polyvinylpyrrolidone, etc." (paragraph [0044]) as examples of thickeners, and mixing the thickener with pure water, an acidic composition comprising an acid such as citric acid or succinic acid, and a carbonate salt such as sodium bicarbonate (which can be used as such, or after grinding in the case of crystalline materials, or after dissolving or dispersing

in (a) suitable solvent(s)), to obtain a composition for percutaneous or permucosal absorption of carbon dioxide (paragraph [0089]).

Document 2 (WO 99/24043 A1 (Medion Research Laboratories), 20 May 1999) discloses inventions relating to "viscous compositions containing carbon dioxide, formed by incorporating carbon dioxide in the form of bubbles in a water-containing viscous composition containing one or two or more thickener(s)", and presents examples of thickeners such as "carrageenan", "sodium alginate" and "poly(vinyl alcohol)" (claim 3), states that the "carbon dioxide is obtained by a reaction between an acid and a carbonate salt" (claim 4); presents examples of acids such as "succinic acid", "malic acid", "citric acid" and "sodium dihydrogen phosphate" and carbonate salts such as "ammonium carbonate" and "potassium carbonate", claims a "kit ... which includes an acid and a water-containing viscous composition containing a carbonate salt" (claim 7) and a "kit which includes a carbonate salt and a water-containing viscous composition containing an acid" (claim 8), and states that a "... carbon dioxide-containing viscous composition ... can be impregnated into an absorbent material such as gauze or sponge, or these materials can be formed into a bag and the composition inserted therein and affixed to the site of usage. An even greater effect can be expected if combined with occlusive dressing, wherein the site to which said composition has been applied or attached is covered with a material such as a film or dressing which has poor permeability to air" (description, page 14, line 11-5 from bottom).

#### Claims 1-12

The inventions set forth in claims 1-12 do not involve an inventive step in the light of documents 1 and

2, cited in the international search report.

Documents 1 and 2 disclose compositions of carbon dioxide for external use, and also disclose of kits for carbon dioxide for external use, comprising a carbonate salt and a water-containing viscous composition containing an acid. The "water-containing viscous composition containing an acid" and "carbonate salt" here are equivalent to the "base agent" and "reactant", respectively, in the present international application; and it is clear that the reaction between these generates carbon dioxide. Moreover, documents 1 and 2 further disclose the possibility of application of the composition for external use impregnated into a material such as sponge.

Given the disclosures in documents 1 and 2, attempting impregnation of the "water-containing viscous composition containing an acid" into a sponge and then reacting this with a "carbonate salt", as an alternative to impregnation of the composition of carbon dioxide for external use into the sponge after reacting the "water-containing viscous composition containing an acid" with the "carbonate salt", as in these documents, is such as might be attempted by a person skilled in the art in the course of ordinary investigation.

It should be noted that the present international application specifies that the carbon dioxide is "dissolved in a non-bubble state"; however, this is merely the result of impregnation into a sponge or the like, and the question of whether this is specified or not cannot be considered to constitute a difference between the present international application and documents 1 and 2.